

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-3E68BAF8-62CB-4E3F-B0A8-8E8E50D7672C_2_en-US
DOI: https://doi.org/10.31003/USPNF_M12550_02_01
DOI Ref: 74mdn

© 2025 USPC
Do not distribute

Carbamazepine Oral Suspension

DEFINITION

Carbamazepine Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of carbamazepine (C₁₅H₁₂N₂O).

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy:](#) 197S▲ (CN 1-May-2020)

Sample solution: Place 5 mL of Oral Suspension in a separator containing 20 mL of 0.1 N sodium hydroxide, and extract with 25 mL of chloroform. Pass the extract through anhydrous sodium sulfate supported on filter paper into a beaker. Wash the anhydrous sodium sulfate with 10 mL of chloroform, and add the washing to the extract. Evaporate the chloroform extract to dryness with the aid of a stream of nitrogen. Dissolve the residue in 10 mL of methylene chloride.

Acceptance criteria: Meets the requirements

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Solution A: Add 0.5 mL of triethylamine and 0.5 mL of formic acid to 1000 mL of water.

Solution B: Add 0.25 mL of formic acid to 1000 mL of methanol.

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	80	20
3.0	80	20
12.0	60	40
18.0	45	55
20.0	45	55
20.1	80	20
23.0	80	20

Diluent: Methanol

System suitability solution: 0.002 mg/mL each of [USP Carbamazepine RS](#) and [USP Carbamazepine Related Compound A RS](#) in *Diluent*

Standard solution: 0.1 mg/mL of [USP Carbamazepine RS](#) in *Diluent*

Sample solution: Nominally 0.1 mg/mL of carbamazepine from a volume of Oral Suspension prepared as follows. Weigh and transfer freshly mixed Oral Suspension equivalent to 20 mg of carbamazepine to a 200-mL volumetric flask. Add about 140 mL of *Diluent*, shake by mechanical means for about 30 min, sonicate for about 2 min, and dilute with *Diluent* to volume. Pass through a suitable filter of 0.2-µm pore size.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 2.1-mm × 10-cm; 1.8-µm packing L10

Column temperature: 40°

Flow rate: 0.3 mL/min

Injection volume: 2 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.7 between carbamazepine related compound A and carbamazepine, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carbamazepine ($C_{15}H_{12}N_2O$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Carbamazepine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of carbamazepine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **UNIFORMITY OF DOSAGE UNITS (905):** Meets the requirements for oral suspension packaged in single-unit containers
- **DELIVERABLE VOLUME (698):** Meets the requirements for oral suspension packaged in multiple-unit containers

IMPURITIES

• **ORGANIC IMPURITIES**

Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.002 mg/mL each of [USP Carbamazepine RS](#), [USP Carbamazepine Related Compound A RS](#), and [USP Carbamazepine Related Compound B RS](#) in *Diluent*

Sample solution: Nominally 1.0 mg/mL of carbamazepine from a volume of Oral Suspension prepared as follows. Weigh and transfer freshly mixed Oral Suspension equivalent to 50 mg of carbamazepine to a 50-mL volumetric flask. Add about 35 mL of *Diluent*, shake by mechanical means for about 30 min, sonicate for about 2 min, dilute with *Diluent* to volume, and shake for about 5 min. Pass through a suitable filter of 0.2-µm pore size.

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.7 between carbamazepine related compound A and carbamazepine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbamazepine related compound B in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of carbamazepine related compound B from the *Sample solution*

r_S = peak response of carbamazepine related compound B from the *Standard solution*

C_S = concentration of [USP Carbamazepine Related Compound B RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of carbamazepine in the *Sample solution* (mg/mL)

Calculate the percentage of each individual unspecified impurity in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each unspecified impurity from the *Sample solution*

r_S = peak response of carbamazepine from the *Standard solution*

C_S = concentration of [USP Carbamazepine RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of carbamazepine in the *Sample solution* (mg/mL)